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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/717,226

11/19/2003

Ji-Young Kim

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FOX ROTHSCHILD LLP
PRINCETON PIKE CORPORATE CENTER
2000 Market Street
Tenth Floor
Philadelphia, PA 19103

EXAMINER

ROBERTS, LEZAH

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/717,226	Applicant(s) KIM ET AL.	
	Examiner LEZAH W. ROBERTS	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 158-164, 166-202, 205-207, 215 and 216 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 158-164, 166-202, 205-207, 215 and 216 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' arguments, filed August 3, 2009 in the Request for Continued Examination, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims

Priority

Applicant's arguments of Leaderman not being competent prior art because the publication date is October 1, 2002 and the priority date is November 9, 2000 appears to be incorrect. The claims recite the contact area width, which does not appear to be disclosed in the priority documents and thus do not receive the earliest priority date of March 17, 2000.

Claim Rejections - 35 USC § 103 – Obviousness (Previous Rejection)

Claims 158-164, 166-202, 205-207, 215 and 216 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leaderman (US 6,458,380) in view of Gallopo et al. (US 2001/0002252) and Sagel et al. (US 5,891,453).

Applicant's Arguments

The combined teachings of all the references combined fail to meet every limitation of the present claims. None of the cited references disclosed the limitations recited in the instant claim (see page 11 of Remarks). Leaderman never discloses the combination of PVP, and hydrogen peroxide in any formulation. Leaderman makes a reference in passing to polyvinyl at col. 4, lines 4-5 of his Patent, but not in context for stabilizing hydrogen peroxide or use with hydroxypropyl methyl cellulose and tripolyphosphates. Accordingly, without employing improper hindsight, there would have been no motivation to make the modifications suggested by the Examiner. Gallopo is not in the same field of endeavor as Leaderman or Sagel and thus not even combinable with their teachings. Those of ordinary skill in the art would not have considered Gallopo's teachings for combination with either Leaderman or Sagel. It further fails to teach the combination of PVP with hydrogen peroxide, hydroxypropyl methylcellulose and sodium tripolyphosphate. Sagel does neither remedy the shortcomings of Leaderman nor the shortcomings Gallopo. Sagel specifically fails to mention the use of PVP and hydroxypropyl methylcellulose. Therefore, even if combined, the teachings of the cited references would have failed to meet all the limitations in the present claims.

Examiner's Response

The Examiner disagrees and submits that Leaderman suggests the combination of hydrogen peroxide, polyvinylpyrrolidone (PVP) and hydroxypropyl methyl cellulose. Sagel further supports this combination by disclosing PVP may be used as an adhesive in whitening strips comprising hydrogen peroxide. Further the claims do not recite that

Art Unit: 1612

PVP stabilizes hydrogen peroxide, they only suggest that these polymers provide adhesive strength. In regards to Gallopo et al., the reference discloses hydrogen peroxide and polyphosphates as tooth whitening agents usable together. Therefore Gallopo et al. is analogous art because it also teaches tooth whitening agents. One of ordinary skill in the art would look to Gallopo et al. because of its disclosure of tooth whitening agents in an oral composition. In regard to Sagel, it suggests using PVP as an adhesion agent and Leaderman suggests hydroxypropyl methyl cellulose thereby meeting the limitations of the instant claims.

Claim Rejections - 35 USC § 103 -Obviousness (New Rejection)

It is believed that the above rejection encompasses all the limitations but for *arguendo*, and in order to ensure completeness of prosecution, the following rejection is made.

Claims 158-164, 166-202, 205-207, 215 and 216 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leaderman (US 6,458,380) in view of Gallopo et al. (US 2001/0002252), Tapolsky et al. (US 6,159,498) and Sagel et al. (US 5,891,453).

Leaderman has previously been discussed and differs from the instant claims insofar as it does not disclose an example comprising PVP, hydrogen peroxide and

Art Unit: 1612

hydroxypropyl methyl cellulose or that the compositions comprise sodium tripolyphosphate or the contact area width.

Gallop et al. has previously been discussed and differ from the instant claims insofar as it does not disclose the compositions are dry patches with the disclosed contact area.

Generally, it is *prima facie* obvious to combine two components, such as two whitening agents hydrogen peroxide and sodium tripolyphosphate, each of which is taught by the prior art to be useful for same purpose, in order to form a third composition to be used for the very same purpose. The idea for combining them flows logically from their having been individually taught in the prior art. See MPEP 2144.06.

The combination of references differ from the instant claims insofar as they do not disclose an example comprising PVP, hydrogen peroxide, polyphosphate and hydroxypropyl methyl cellulose or the contact area width.

Tapolsky et al. has previously been discussed in the Office Action mailed May 3, 2006. The reference discloses the adhesive layer may comprise at least one film-forming water-soluble polymer, usually a cellulose derivative and at least one pharmacologically acceptable polymer known for its bioadhesive capabilities. The film forming polymer used includes hydroxyethyl cellulose and hydroxypropyl methylcellulose (col. 5, lines 44-47). The bioadhesive polymer of the adhesive layer includes polyvinylpyrrolidone (PVP) (col. 5, lines 61-63). These bioadhesive polymers are preferred because they have good and instantaneous mucoadhesive properties in a dry, film state, which meets the limitation "wherein the patch has adhesive strength" and

“as an adhesive polymer”. The reference differs from the instant claims insofar as it does not teach using peroxide or sodium tripolyphosphate in the compositions.

It would have been obvious to one of ordinary skill in the art to have used a combination of PVP and hydroxypropylmethyl cellulose in the compositions of the combined teachings of Leaderman and Gallopo et al. motivated by the desire to make a whitening compositions that has good adhesion to the oral cavity when in a dry state as disclosed by Tapolsky et al.

The combination of references differs from the instant claims insofar as it does not disclose the contact area with.

Sagel et al. has previously been discussed and differs from the instant claims insofar as it does not disclose the compositions are dry or comprise tripolyphosphate.

It would have been obvious to one of ordinary skill in the art to have made the delivery systems of the combined references of Leaderman, Gallopo et al. and Tapolsky et al. with the dimensions disclosed by Sagel et al. wherein the width ranges from 0.5 to 4 cm motivated by the desire to make sure the system is an appropriate size to cover the teeth to provide adequate whitening.

In regards to claims 166, 167, 181, 182, 196, and 197, generally, it is *prima facie* obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended use. See MPEP 2144.07. It would have been obvious to have added plasticizers to the delivery systems of the combined references of Leaderman, Gallopo et al. and Tapolsky motivated by the desire to use components

Art Unit: 1612

for their known function of being a carrier used in teeth whitening delivery systems as disclosed by Sagel et al.

Obvious-Type Double Patenting (New Rejection)

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 158-164, 166-202, 205-207, 215 and 216 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 15-30 of copending Application No. 11/414,435 in view of Tapolsky (US 6,159,498).

The claims are coextensive because both sets of claims read on a whitening patch comprising hydrogen peroxide, polyvinyl pyrrolidone and sodium tripolyphosphate. The two sets of claims differ from one another insofar as the instant

Art Unit: 1612

claims are species claims to the copending claims and the instant claims require a mixture of hydroxypropylmethyl cellulose and polyvinyl pyrrolidone.

The secondary reference teaches different types of celluloses combined with polyvinyl pyrrolidone (PVP) make good bioadhesives.

It would be obvious to one of ordinary skill in the arts to have mixed hydroxypropyl methyl cellulose with PVP in the composition of the copending claims motivated by the desire produce a whitening compositions that has good adhesiveness as disclosed by the secondary reference.

This is a provisional obviousness-type double patenting rejection.

Claims 158-164, 166-202, 205-207, 215 and 216 are rejected.

Claims 158-164, and 166-172 are objected.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone

Art Unit: 1612

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612